

510(k) SUMMARY FOR FREEDOM OF INFORMATION

IGEL® 56 (hefilcon C) SOFT (hydrophilic) CONTACT LENS
FOR DAILY WEAR

1. Submitted by: Igel Vision Care PTE, Ltd
139 Joo Seng Road, #06-01
ATD Centre
Singapore 368362

Contact: John M. Szabocsik, Ph.D.
Official agent Szabocsik and Associates
203 N. Wabash, Ste 1200
Chicago, IL 60601
(312) 553-0828
2. Date prepared: June 5, 1998
3. Device:
Common Name Igel® 56 (hefilcon C) Soft (hydrophilic)
Contact Lens
Trade Name Igel® 56 (hefilcon C) Soft (hydrophilic)
Contact Lens
4. Classification Class II (Performance Standards)
21 CFR 886.5925
Soft (hydrophilic) contact lens
5. Substantial
equivalence This product is substantially
equivalent to other currently marketed
hefilcon lenses, such as Gold Medalist
Toric lenses
6. Device
description The Igel® 56 (hefilcon C) soft
(hydrophilic) contact lens is a
hemispherical, flexible transparent
shell of the following dimensions:

Sphere: Chord diameter: 14.2mm
Center thickness: 0.09mm (at -3.00 D)
Optic Zone: variable optic zone
with power
Base Curve: 8.60mm
Power: -0.50D to -8.00D (in
0.25D steps); -8.50D
to -12.00D (in
0.50D steps); +0.50D
to +6.00D (in 0.25D
steps)

Toric: Chord diameter: 14.6mm
Center thickness: 0.15mm
Optic Zone: 8.45mm
Base Curve: 8.70mm
Sphere: Plano to -8.00 D (in 0.25 D steps)
Plano to +6.00 D (in 0.25 D steps)
Cylinder: up to 7.00 D
Axis: 80, 90, 100, 160, 170, 180, 10
& 20°

The lens material (hefilcon C) is a copolymer of 2 hydroxethylmethacrylate and N-vinyl pyrrolidinone. The blue tinted lens also contains D&C Green #6. The apparent color of the visibility tint may decrease slowly following repeated disinfection, but this will not affect the safety or performance of the lenses. When fully hydrated, the lens is 56% water by weight.

7. Intended use: The Igel®56 (hefilcon C) Soft (hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism, for the spherical lens up to 1.50 diopters that does not interfere with visual acuity, and for the toric lens up to 7.00 diopters) in not-aphakic persons with non-diseased eyes. The lens may be disinfected using chemical disinfecting systems only.

8. Comparison to predicate devices: see following table

Igel® 56 Summary for FOI

SUBSTANTIAL EQUIVALENCE

Material	Igel® 56 hefilcon C	Gold Medalist™ Toric hefilcon C
Description	random copolymer of 2-hydroxyethyl methacrylate and N- vinyl-2-pyrrolidone	random copolymer of 2-hydroxyethyl methacrylate and N- vinyl-pyrrolidone
Water Content	56% in buffered saline	57% in normal saline
Specific Gravity	1.16	1.1
Refractive Index	1.41 (hydrated)	1.41
Light Transmittance (visible)	94.5% (clear) 90.3% (blue handling tint)	at least 90%
Oxygen permeability	21×10^{-11} (cm/sec)(ml O ₂ /mlxmm Hg) Measured at 35°C (Fatt method).	17×10^{-11} (cm/sec)(ml O ₂ /mlxmm Hg) Measured at 35°C (Fatt method).
Actions	When placed on the human cornea, the hydrated Igel® 56 (hefilcon C) Soft (hydrophilic) Contact Lens acts as a corrective refracting medium to focus light rays on the retina.	In its hydrated state, the Bausch & Lomb Gold Medalist™ Toric (hefilcon C) Visibility Tinted Contact Lens when placed on the cornea acts as a corrective refracting medium to focus light rays on the retina.
Chord Diameter*	14.2mm	12.0 to 18.0mm
Center thickness*	0.09mm (at -3.00D)	0.02mm to 1.0mm
Base Curve*	8.6mm	8.3mm to 9.2mm
Powers (Spherical) (Cylinder)	-12.00 to +6.00D up to 7.00D	+20.00 to -20.00D up to 5.00D
Optical Zone	vary with power	

Introduction

The Igel® 56 (hefilcon C) Soft (hydrophilic) Contact Lens is a spherical lens for the correction of near-sightedness (myopia) and farsightedness (hyperopia). A toric version of the same lens is able to correct for astigmatism from 0.50D to 7.00D.

Contained in the submission are comparisons of the product to the predicate device, information on the chemistry and manufacturing, results of toxicological and microbiological tests, and the report of a clinical trial of 37 subjects, who have used the product over a period of four weeks.

I. Chemistry and Manufacturing

The lens material (hefilcon C) is a copolymer of 2 hydroxethylmethacrylate and N-Vinyl pyrrolidinone. The blue tinted lens also contains D&C Green #6. The apparent color of the visibility tint may decrease slowly following repeated disinfection, but this will not affect the safety or performance of the lenses. When fully hydrated, the lens is 56% water by weight.

The Igel® 56 (hefilcon C) Soft (hydrophilic) Spherical Contact Lens is a hemispherical, flexible transparent shell of the following dimensions:

Chord diameter:	14.2mm
Center thickness:	0.09mm (at -3.00 D)
Optic Zone:	variable optic zone with power
Base Curve:	8.60mm
Power:	-0.50D to -8.00D (in 0.25D steps) -8.50D to -12.00D (in 0.50D steps) +0.50D to +6.00D (in 0.25D steps)

The Igel® 56 (hefilcon C) Soft (hydrophilic) Toric Contact Lens has the following characteristics:

Chord diameter:	14.6mm
Center thickness:	0.15mm
Optic Zone:	8.45mm
Base Curve:	8.70mm
Sphere:	Plano to -8.00 D (in 0.25 D steps) Plano to +6.00 D (in 0.25 D steps)
Cylinder:	up to 7.00 D
Axis:	80, 90, 100, 160, 170, 180, 10 & 20
Stabilizing Mechanism:	Dynamic Stabilizing Sectors

Igel® 56 Summary for FOI

The physical properties of the lens (sphere or toric) are as follows:

Specific Gravity:	1.16
Refractive index:	1.41 (hydrated)
Light transmission:	94.5% (clear)
	90.3% (blue handling tint)
Surface character:	hydrophilic
Water content:	56% weight in normal buffered saline
Tensile strength:	2.85 kg/cm ²
Elongation:	72%
Modulus of Elasticity:	5.20 kg/cm ²
Oxygen permeability:	D _x : 21×10^{-11} (cm/sec)(ml O ₂ /mlxmm Hg) Measured at 35°C (Fatt method).

A. Extractables

Samples of lenses were extracted in saline, and the extracts analyzed by high performance liquid chromatography to determine if any monomers were extracted from the material. There were no extractables detected.

B. Process validation

The manufacturing process for this cast-moulded lens was shown to be valid both for lens quality and sterility.

II. Toxicology

The toxicological testing is summarized below. The lens material was shown to be non-toxic in all tests.

A. Agar Overlay Cytotoxicity:

Igel® 56 (hefilcon C) Soft (hydrophilic) Contact Lenses were tested in a direct contact cytotoxicity assay. The lenses were noncytotoxic.

B. Systemic toxicity:

Saline and cottonseed oil extracts of Igel® 56 (hefilcon C) Soft (hydrophilic) Contact Lenses were evaluated for systemic toxicity by intraperitoneal (ip) injection in healthy mice, 50ml/kg body weight. The animals were observed over a 72 hour period, and showed no difference from control animals. The lenses passed the test requirements, that there be no difference between the response of test and control animals.

Igel® 56 Summary for FOI

C. Acute Ocular irritation:

Saline and cottonseed oil extracts of Igel® 56 (hefilcon C) Soft (hydrophilic) Contact Lenses were evaluated for ocular irritation by instillation into the inferior ocular cul-de-sac of rabbits. The eyes were examined over a 72 hour period and showed no irritation.

III. Microbiology

A. Sterility

The Igel® 56 (hefilcon C) Soft (hydrophilic) Contact Lenses passed the requirements of sterility testing.

B. Stability

Accelerated shelf-life testing has demonstrated a shelf-life in excess of 16 months. Sterility stability testing, accelerated and real-time, continue.

IV. Clinical Studies

A clinical trial of 4 weeks usage of the Igel® 56 (hefilcon C) Soft (hydrophilic) Contact Lenses by 37 subjects, wearing lenses on a daily wear schedule, showed that the product is substantially equivalent to other lenses available on the market. The clinical summary follows.

The study was conducted over 1 month of wear, subjects being seen initially, and after 1, 2 and 4 weeks. The study was initiated July 11, 1997 and completed August 19, 1997.

Two (2) investigators enrolled a total of 37 test subjects. The age range of the test population was from 17 to 61, with 26 (70.3%) females and 11 (29.7%) males.

Of the 37 subjects, 35 (94.6%) completed 1 month of wear, and 2 (5.4%) discontinued.

FINDINGS

a. SAFETY:

(1) Adverse Reactions

The FDA regulations for medical devices (21 CFR 812.3) define an unanticipated adverse device effect as:

"any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem or death was not previously

identified in nature, severity or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that related to the rights, safety or welfare of the subject"

There were no adverse events during this study.

(2) Slit Lamp Findings:

A positive slit lamp finding is a routinely occurring complication that can be expected with or without the presence of contact lenses. The degree of severity may range from very slight, representing no medical concern, to serious, requiring medical treatment.

Table B shows the incidence of slit lamp findings in the investigational group at the initial and final visits.

The slit lamp finding listed as "Other" at the initial visit was an old healed neovascularization.

TABLE B

FINDINGS	<u>INCIDENCE OF SLIT LAMP</u>	
	INITIAL	FINAL
NO FINDINGS ^a	51.4	58.6
EDEMA ^b	0.0	0.0
NEOVASCULAR	18.9	11.4
STAINING	5.4	1.4
INJECTION	0.0	0.0
TARSAL	48.6	40.0
OTHER	1.4	0.0

^a Percent of eyes examined with no findings, regularly scheduled visits only

^b Percent of eyes with finding, regularly scheduled visits only

(3) Symptoms, Problems and Complaints:

Symptoms, problems and complaints were reported by the investigators at each visit. Lens awareness, handling problems and reading problems were the most frequently reported symptoms among all subjects. Table C shows the overall incidence of these selected symptoms.

The "other" symptoms were dryness (reported by 2 subjects); torn lenses reported by 1 subject.

TABLE C

SELECTED SYMPTOMS, PROBLEMS AND COMPLAINTS

SYMPTOM	Incidence
NONE*	62.6%
LENS AWARENESS ^b	14.5%
HANDLING PROBLEMS	8.4%
READING PROBLEMS	7.9%

- * Percent of eyes examined with no findings, regularly scheduled visits only
- ^b Percent of eyes with finding, regularly scheduled visits only

(4) Discontinuations:

Throughout the study, 2 subjects (5.4%) were discontinued.

D. EFFICACY:

(1) Visual Acuity:

All but 2 eyes had a final visual acuity within 1 line of the initial best corrected acuity. The appropriate acuity was achieved by all eyes, since those two eyes were in subjects fit for monovision.

(2) Wear Time:

Wear time remained essentially unchanged over the one month of the study, indicating continuing comfort and cleanliness with the investigational solution.

(3) Lens Cleanliness:

Lenses were evaluated at each visit, according to a modified Rudko classification. Overall, the reports of the Rudko evaluation showed that 91% of test lenses were clinically clean during the study. (Rudko grades I and II are considered clinically clean.)

These results confirm that the Igel® 56 (hefilcon C) Soft (hydrophilic) Contact Lenses are effective in the correction of myopia and hyperopia.

Gender Comparisons:

The overall test population was 70.3% female, 29.7% male, and the visit distribution over the study was 69% female, 31% male. Overall, there were no slit lamp findings at 58% of the visits; among females, at 63%, among males at 47% of the visits. There were no symptoms reported at 61% of the visits; among females, no symptoms were reported at 64%, among males, at 56%. There is no significant difference in the findings, and no further analysis was warranted. Because of the small sample size, the gender analysis may be statistically irrelevant.

OVERALL CONCLUSION OF THE CLINICAL STUDY:

The data of the clinical trial confirm that the Igel® 56 (hefilcon C) Soft (hydrophilic) Contact Lenses are substantially equivalent to currently marketed lenses in safety and efficacy.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 6 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Igel Vision Care PTE, Ltd.
c/o John M. Szabocsik, Ph.D.
Szabocsik and Associates
203 N. Wabash, St. 1200
Chicago, IL 60601

Re: K974837

Trade Name: IGEL ® 56 (hefilcon C) soft (hydrophilic) Contact Lens for Daily Wear (clear or
visiting, cast molded)

Regulatory Class: II

Product Code: 86 LPL

Dated: June 8, 1998

Received: June 9, 1998

Dear Dr. Szabocsik:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

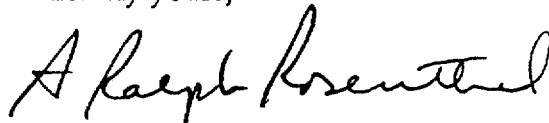
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Dr. John Szabocsik

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "A. Ralph Rosenthal". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN) K974837DEVICE NAME IGEL® 56 (hefilcon C) SOFT
(HYDROPHILIC) CONTACT LENS

INDICATIONS FOR USE

The Igel®56 (hefilcon C) Soft (hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism, for the spherical lens up to 1.50 diopters that does not interfere with visual acuity, and for the toric lens up to 7.00 diopters) in not-aphakic persons with non-diseased eyes. The lens may be disinfected using chemical disinfecting systems only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON
ANOTHER PAGE IF NEEDED)

Mig-Chuan Shai J
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per

21 CFR 801.109)

(Optional Format 1-2-96)